REMARKS

Claims 1, 4-8, 10-38 and 40-54 remain pending herein. Claims 2, 3, 9 and 39 are hereby canceled without prejudice or waiver of the right to pursue the subject matter of said claims in another application. No new claims have been added. Claims 1, 8, 10, 12, 17, 18, 29, 31-37, 40, 43-44, and 52-53 have been amended. All other claims remain the same. Reconsideration of the claims as pending is respectfully requested.

The specification (page 42) has been amended to include the subject matter of originally filed claims 4 and 25.

Claims 1-5, 10, 13-14, and 18-38 stand rejected under 37 C.F.R. §112, 1st para. for scope of enablement because the specification does not reasonably provide enablement for the employment of any COX-II inhibitors and any muscle relaxants recited in the claims. Insofar as it may apply to the present claims, the rejection is respectfully traversed.

The specification (pages 7-10) includes recitation of a large list of COX-II inhibitors that are suitable for use according to the invention. As required, the list specifically names compounds by their names. Moreover, it includes patent citations disclosing the names and structures of suitable COX-II inhibitors and methods of preparing them. The specification (page 10) also includes recitation of a list of suitable muscle relaxants that can be used according to the invention. Those compounds are well known and commercially available. Accordingly, one of ordinary skill in the art can readily visualize or recognize the identity of the members of the genus.

The specification (page 11) discloses some of the salt forms in which the compounds can be administered as well as some general methods for their preparation. The drug combination can be administered in any of a number of different dosage forms (pages 12, 30), which methods of preparation are described (pages 12-31) and exemplified (Examples 1-13).

Applicants submit that, if taken out of context, the terms "COX-II inhibitor" and "muscle relaxant" might be deemed as lacking sufficient definition; however, Applicant is his own lexicographer, and use of applicant's term(s) in a claim is permissible provided it is sufficiently well defined in the specification. As noted above, the terms are exemplified with specific compounds and thus defined to the extent required by law.

Examiner states that the claimed invention is highly unpredictable, since one skilled in the art cannot fully describe [the] genus, visualize or recognize the identity of the members, etc.

... Applicants respectfully submit that the listing of compounds on pages 7-10 describes the genus and thus allows an artisan of ordinary skill in the art to visualize or recognize the identity of the members.

Suggested dosages, weight ratios and amounts for the drugs are disclosed (amended page 42, original page 29, original examples 1-13, and original claims 4, 14, 25). Beginning with the suggested dosages, amounts and weight ratios, Applicants submit that one of ordinary skill in the art will be able to identify a suitable operating range for combinations of different COX-II inhibitors and muscle relaxants.

Absent any evidence to the contrary, Applicants respectfully submit that the specification enables the scope of compounds as claimed.

Applicants respectfully submit that the rejection of claims 1-5, 10, 13-14, and 18-38 under 37 C.F.R. §112, 1st para. has been overcome and request that it be withdrawn.

Claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 stand rejected under 35 U.S.C. §112, 2nd para. as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Insofar as it may apply to the present claims, this rejection is traversed.

While Examiner has stated that terms, such as "delayed release", "immediate release", "slow release", and "rapid release", lack definition, those same terms are widely used and well understood in the pharmaceutical sciences, in particular U.S. patents covering pharmaceutical dosage forms. There are literally hundreds, if not thousands, of U.S. patents and publications of the Food and Drug Administration that use these exact same terms. As evidence thereof, Applicants submit Exhibits A-F. Exhibits A-D contain lists of U.S. Patents that include those very same terms in the claims: "delayed release" (Exhibit A), "immediate release" (Exhibit B), "slow release" (Exhibit C), "rapid release" (Exhibit D). Exhibit E contains the first page information for the CDER Data Standards Manual for dosage forms (http://www.fda.gov/cder/dsm/DRG/drg00201.htm) published by the FDA. This on-line publication specifically defines the terms "slow release", "extended release", "delayed release". Moreover, the exhibits provided along with the Response mailed September 17, 2002 also define these terms. Without further explanation by Examiner, Applicants do not understand how textbook definitions can be unclear. Exhibit F contains a citation of the Guidance for Industry: dissolution testing of immediate release solid oral dosage forms

(http://www.fda.gov/cder/guidance/1713bp1.pdf) published by the FDA. This on-line publication specifically defines and characterizes an "immediate release" dosage form. Accordingly, Applicants submit that the terms "rapid release", "immediate release", "slow release", and "delayed release" are well-defined terms of art in the pharmaceutical sciences.

It is well known in the art to combine different types of drug release profiles to achieve particular clinical effects. For example a "delayed but rapid release" dosage form would provide rapid release of drug AFTER expiration of a delay (lag) period.

While Applicants vehemently disagree with Examiner's conclusion, Applicants have amended the claims to define the invention with other language that does not rely upon the terms "rapid", "slow", "immediate" or "delayed". Applicants submit that such definition is merely intended to clarify the language of the claims as originally filed and not narrow their scope.

Accordingly, Applicants submit that the rejection of claims 7-8, 12, 14, 16-18, 22-23, 28-29, 31-37, 43-45 and 52-54 under 35 U.S.C. §112, 2nd para. has been overcome and request that it be withdrawn.

Claims 7-8, 16-17 and 40-48 stand rejected under 35 U.S.C. §112, 2nd para. for use of the terms SC-5766, SC-58215, and T-614, which Examiner has indicated as a trademark or trade name. Insofar as it may apply to the present claims, this rejection is traversed.

As previously noted, the terms SC-5766, SC-58215, and T-614 are not trademarks or trade names. Nonetheless, applicants have replaced the terms with their corresponding chemical names.

Accordingly, Applicants submit that the rejection of claims 7-8, 16-17 and 40-48 under 35 U.S.C. §112, 2nd para. has been overcome and request that it be withdrawn.

Claims 1-8, 10-38 and 40-54 stand rejected under 37 C.F.R. §103(a) as being unpatentable over Burch et al. in view of Okada et al. (US 5,476,663). Insofar as it may apply to the present claims, this rejection is respectfully traversed.

Claim 1 has been amended to include the subject matter of original claims 2 and 3 and previously considered subject matter concerning the additive or synergistic therapeutic effect that the combination of a COX-II inhibitor and muscle relaxant provides when administered to a subject (See prior Office Actions and corresponding responses; see page 5, lines 24-25 and page 29, line 26 to page 30, line 9 of the specification). Claim 10 has been amended to include the subject matter of original claims 2 and 3

Applicants agree with Examiner that the prior art (Burch et al.) does not expressly disclose a COX-II inhibitor, e.g. rofecoxib, in combination with a muscle relaxant, e.g. pridinol, in a pharmaceutical dosage form. Applicants also agree with Examiner that the discovery or expectation of synergistic analgesic effect is unexpected.

Applicants disagree, however, that Burch et al. suggest the combination of a COX-II inhibitor and a muscle relaxant. Burch et al. is specifically directed to the combination of an analgesic and a COX-II inhibitor. It is well known in the industry that an analgesic and a muscle relaxant have different therapeutic indications and mechanisms of action. Accordingly, the disclosure of Burch et al. fails to suggest the invention as claimed.

Combination of the disclosures of Burch et al. and Okada et al. also fails to suggest the invention as claimed. Applicants disagree that Okada et al. teaches that a muscle relaxant such as pridinol is useful in combination with analgesic and/or anti-inflammatory drugs (Col. 3, lines 13-28). Applicants respectfully submit that pridinol is merely included among a laundry list of compounds that can be included in the dosage form of Okada et al. In fact, a thorough search of Okada et al. reveals that they failed to even suggest the simultaneous administration of two or more drugs with their dosage form. In each case, the drugs are administered individually. The only combinations they suggest or disclose are combinations of excipients, the inactive agents. Accordingly, while the combination of Burch et al. and Okada et al. might suggest a COX-II inhibitor from Burch et al. with an analgesic drug chosen from the list Okada et al., the combination would not suggest a COX-II inhibitor and a muscle relaxant. Burch et al. would not be motivated to include a muscle relaxant from Okada et al., since such a prophetic combination would not include the analgesic agent that Burch et al. specifically requires. Moreover, the courts have clearly established that mere recitation of Applicants' claimed elements within the text of a prior art reference is insufficient to establish obviousness. The prior art must also suggest the combination of those elements and the expectation of success in using the suggested combination as proposed to be claimed by an applicant.

Examiner has indicated that the Supplemental Declaration under Rule 37 C.F.R. §1.132 of Dr. Feleder, mailed September 17, 2002, was insufficient to overcome the finding of *prima facie* obviousness, since it did not include "factual evidence" establishing the observed synergistic effect of the claimed drug combination. Applicants submit herewith a second Supplemental Declaration that includes the actual data obtained from the *in vivo* study described

therein. The data for the treated animals were normalized against the data for the control animals in order to establish a relevant scale for comparison. The data demonstrate that the combination of rofecoxib and pridinol provides a synergistic effect, but the combination of diclofenac (analgesic) and pridinol does not. Applicants submit that the claimed combination provides an unexpectedly enhanced analgesic therapeutic benefit. Accordingly, the claimed combination is not *prima facie* obvious and is therefore patentable over the art of record.

In view of the above, applicants submit that the rejection of claims 1-8, 10-38 and 40-54 under 37 C.F.R.§103(a) has been overcome and request that it be withdrawn.

A marked-up copy of the claims and of the specification as amended is attached hereto. Entry of the amendments indicated thereon into the record is requested. In view of all the foregoing, Applicants respectfully submit that the pending claims are patentable over the art of record and in form for allowance. An early notice of allowance thereof is requested.

Respectfully submitted,

Date: 10/23/3

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CLAIMS

We claim:

1) (Currently amended) A pharmaceutical composition comprising:
   a) a COX-II inhibitor, wherein the COX-II inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically;
   b) a muscle relaxant; and
   c) at least one pharmaceutical excipient; wherein the COX-II inhibitor and muscle relaxant provide an additive or synergistic therapeutic effect when administered to a subject.
2) (Cancelled)
3) (Cancelled)
4) (Original) The pharmaceutical composition of claim 1, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8).
5) (Original) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected from the group consisting of central muscle relaxants and neuromuscular blocking agents.
6) (Original) The pharmaceutical composition of claim 1, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbents, alkalizing agent, antioxidants, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.
7) (Previously amended) The pharmaceutical composition of claim 1, wherein the muscle relaxant is selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisione, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.
8) (Thrice Amended) The pharmaceutical composition of claim 1, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib, celecoxib, flosulide, [~~NS-398~~] N-(2-

~~cyclohexyloxy-4-nitrophenyl)~~ methanesulfonamide, [~~DUP-697~~] ~~5-bromo-2-(4-fluorophenyl)-3-(4-methylsulfonyl)~~ thiophene, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, [~~SC-57666~~] ~~1-fluoro-4-(2-(4-(methylsulfonyl)-phenyl)-1-cyclopenten-1-yl)-benzene~~, [~~T-614~~] ~~N-(3-formylamino-4-oxo-6-phenoxy-4H-chromen-7-yl)~~ methanesulfonamide, and combinations thereof.

9) (Canceled)

10) (Currently amended) A pharmaceutical dosage form comprising:

a) a therapeutically effective amount of a COX-II inhibitor, ~~wherein the COX-II inhibitor binds COX-II receptors selectively over COX-I receptors or binds COX-II receptors specifically~~;

b) a therapeutically effective amount of a muscle relaxant; and

c) at least one pharmaceutical excipient.

11) (Original) The pharmaceutical dosage form of claim 10, wherein the dosage form is selected from the group consisting of a gel, cream, ointment, pill, tablet, capsule, liquid, suspension, osmotic device, bead, granule, spheroid, particulate, paste, prill, reconstitutable solid, powder, and injectible liquid.

12) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the [~~dosage form independently provides a controlled, delayed, sustained, immediate, timed, slow or rapid release of each of the~~] COX-II inhibitor is ~~released at a faster rate than~~ [~~and~~] the muscle relaxant, ~~the COX-II inhibitor is released at a slower rate than the muscle relaxant, or the COX-II inhibitor is released at approximately the same rate as the muscle relaxant when the dosage form is~~ [~~when~~] exposed to an aqueous environment.

13) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutically effective plasma levels of the COX-II inhibitor for a period up to at least about 12 hours after administration to a subject.

14) (Previously amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the dosage form provides therapeutically effective plasma levels of the muscle relaxant for a period of administration sufficient to enhance the therapeutic benefit provided by the COX-II inhibitor.

15) (Original) The pharmaceutical dosage form of claim 10, wherein the pharmaceutical dosage form is adapted for oral, buccal, ocular, otic, gastrointestinal, dermal, rectal, vaginal, cervical,

intrauterine, epidermal, transdermal, implant, mucosal, parenteral, sublingual, nasal, or pulmonary delivery.

16) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the muscle relaxant is selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisione, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide.

17) (Thrice amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor is selected from the group consisting of rofecoxib, celecoxib, flosulide, [~~NS-398~~] N-(2-cyclohexyloxy-4-nitrophenyl) methanesulfonamide, [~~DUP-697~~] 5-bromo-2-(4-fluorophenyl)-3-(4-methylsulfonyl) thiophene, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, [~~SC-57666~~] 1-fluoro-4-(2-(4-(methylsulfonyl)-phenyl)-1-cyclopenten-1-yl)-benzene, [~~T-614~~] N-(3-formylamino-4-oxo-6-phenoxy-4H-chromen-7-yl) methanesulfonamide, and combinations thereof.

18) (Twice amended) The pharmaceutical dosage form of claim 10, wherein [~~each drug is released rapidly and~~] the dosage form provides therapeutically effective levels of each drug for a period of at least 12 hours after administration to a subject.

19) (Original) The pharmaceutical dosage form of claim 18, wherein the period is about 12 to 60 hours.

20) (Original) The pharmaceutical dosage form of claim 19, wherein the period is about 12 to 30 hours.

21) (Original) The pharmaceutical dosage form of claim 19, wherein the period is about 18 to 48 hours.

22) (Previously amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the plasma level of the COX-II inhibitor or muscle relaxant is dependent upon the plasma level of the muscle relaxant or COX-II inhibitor, respectively.

23) (Previously amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the plasma level of the COX-II inhibitor or muscle relaxant is independent of the plasma level of the muscle relaxant or COX-II inhibitor, respectively.

24) (Original) The pharmaceutical dosage form of claim 10, wherein the dosage form provides therapeutic plasma levels for the muscle relaxant in an amount sufficient to provide a therapeutic benefit to a subject to whom it is administered.

25) (Previously amended) The pharmaceutical dosage form of claim 10, wherein after administration to a subject the dosage form provides therapeutic plasma levels for the COX-II inhibitor in the range of about 90 ng to about 300 ng per ml of plasma in the subject.

26) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released sequentially after exposure to an aqueous environment.

27) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released concurrently after exposure to an aqueous environment.

28) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the COX-II inhibitor and muscle relaxant are released in spaced apart periods of time after exposure to an aqueous environment.

29) (Twice amended) The pharmaceutical dosage form of claim 10, wherein each drug is independently released according to a [~~rapid, immediate,~~] controlled, sustained, [~~slow,~~] timed, targeted, pseudo-first order, first order, pseudo-zero order, or zero-order[~~, and/or delayed~~] release profile after exposure to an aqueous environment, optionally wherein the release of one or both of the drugs begins after expiration of a lag period, and optionally wherein the release of one drug begins after release of the other drug has begun.

30) (Previously amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor and a controlled release of the muscle relaxant after exposure to an aqueous environment.

31) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the COX-II inhibitor after exposure to an aqueous environment and a [~~rapid~~] release of the muscle relaxant within two hours after exposure to an aqueous environment.

32) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the dosage form provides a controlled release of the muscle relaxant after exposure to an aqueous environment and a [~~rapid~~] release of the COX-II inhibitor within two hours after exposure to an aqueous environment.

33) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the dosage form [~~provides a rapid release of~~] releases the COX-II inhibitor and [~~of~~] the muscle relaxant within two hours after exposure to an aqueous environment.

34) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the dosage form [~~provides a rapid release of~~] releases the muscle relaxant within two hours after exposure to an environment of use and [~~a delayed but rapid~~] release of the COX-II inhibitor begins after [~~exposure to an aqueous environment~~] release of the muscle relaxant has begun.

35) (Twice amended) The pharmaceutical dosage form of claim [~~10~~] 34, wherein the dosage form provides a [~~rapid release of the muscle relaxant and a timed but~~] controlled release of the COX-II inhibitor after exposure to an aqueous environment.

36) (Twice amended) The pharmaceutical dosage form of claim 10, wherein the dosage form [~~provides a rapid release of~~] releases the COX-II inhibitor within two hours after exposure to an environment of use, [and a delayed but rapid] release of the muscle relaxant begins after [exposure to an aqueous environment] release of the COX-II inhibitor has begun.

37) (Twice amended) The pharmaceutical dosage form of claim [~~10~~] 36, wherein the dosage form provides a [~~rapid release of the COX-II inhibitor and a timed but~~] controlled release of the muscle relaxant after exposure to an aqueous environment.

38) (Original) The pharmaceutical dosage form of claim 10, wherein the weight ratio of COX-II inhibitor to muscle relaxant varies from 12.5:2.2 to 50:8.

39) (Canceled)

40) (Twice amended) A pharmaceutical composition comprising:

a) a COX-II inhibitor selected from the group consisting of rofecoxib, celecoxib, flosulide, [~~NS-398~~] N-(2-cyclohexyloxy-4-nitrophenyl) methanesulfonamide, [~~DUP-697~~] 5-bromo-2-(4-fluorophenyl)-3-(4-methylsulfonyl) thiophene, meloxicam, 6-methoxy-2-naphthylacetic acid, nabumetone, etodolac, nimesulide, [~~SC-57666~~] 1-fluoro-4-(2-(4-(methylsulfonyl)-phenyl)-1-cyclopenten-1-yl)-benzene, [~~T-614~~] N-(3-formylamino-4-oxo-6-phenoxy-4H-chromen-7-yl) methanesulfonamide, and combinations thereof;

b) a muscle relaxant selected from the group consisting of alcuronium, alosetron, aminophylline, baclofen, carisoprodol, chlorphenesin, chlorphenesin carbamate, chlorzoxazone, chlormezanone, cyclobenzaprine, dantrolene, decamethonium, diazepam, dyphylline, eperisione, ethaverine, gallamine triethiodide, hexafluorenium, mephenesin, metaxalone, methocarbamol, metocurine iodide, orphenadrine, pancuronium, papaverine, pipecuronium, pridinol, succinylcholine, theophylline, tizanidine, tolperisone, tubocurarine, vecuronium, idrocilamide, ligustilide, cnidilide, and senkyunolide and combinations thereof; and

c) at least one pharmaceutical excipient.

41) (Previously added) The composition of claim 40, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.

42) (Previously added) The composition of claim 41, the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8).

43) (Amended) The composition of claim 40, wherein the COX-II inhibitor and muscle relaxant are independently provided in each occurrence in controlled release form, sustained release form, [immediate,] timed release form, [~~slow or rapid release form~~] or in a form wherein complete release of drug occurs within two hours of beginning of its release.

44) (Amended) The composition of claim 43, wherein release of at least one of the COX-II inhibitor and muscle relaxant [~~are independently further provided in each occurrence in delayed or targeted release form~~] begins after expiration of a lag period and/or release of at least one of the COX-II inhibitor and the muscle relaxant is targeted in a subject to which the composition is administered.

45) (Previously added) The composition of claim 40, wherein at least one of the COX-II inhibitor and muscle relaxant are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.

46) (Previously added) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 40.

47) (Previously added) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 41.

48) (Previously added) A pharmaceutical dosage form comprising the pharmaceutical composition of claim 42.

49) (Previously added) A pharmaceutical composition comprising:

a) a COX-II inhibitor selected from the group consisting of rofecoxib and celecoxib;

b) pridinol; and

c) at least one pharmaceutical excipient.

50) (Previously added) The pharmaceutical composition of claim 49, wherein the at least one pharmaceutical excipient is independently selected from the group consisting of an acidifying agent, adsorbent, alkalizing agent, antioxidant, buffering agent, colorant, flavorant, sweetening agent, tablet antiadherent, tablet binder, tablet and capsule diluent, tablet direct compression excipient, tablet disintegrant, tablet glidant, tablet lubricant, tablet or capsule opaquant, plasticizer, surface active agent, solvent, oil, soap, detergent, and tablet polishing agent.

51) (Previously added) The composition of claim 49, the weight ratio of COX-II inhibitor to pridinol varies from (12.5:2.2) to (50:8).

52) (Amended) The composition of claim 49, wherein the COX-II inhibitor and pridinol are independently provided in each occurrence in controlled release form, sustained release form, [immediate,] timed release form, [~~slow or rapid release form~~] or in a form wherein complete release of drug occurs within two hours of beginning of its release.

53) (Amended) The composition of claim 52, wherein release of at least one of the COX-II inhibitor and pridinol [~~are independently further provided in each occurrence in delayed or targeted release form~~] begins after expiration of a lag period and/or release of at least one of the COX-II inhibitor and pridinol is targeted in a subject to which the composition is administered.

54) (Previously added) The composition of claim 49, wherein at least one of the COX-II inhibitor and pridinol are independently provided in each occurrence in pseudo-first order, first order, pseudo-zero order, or zero order release form.

A third composition (forming a drug-containing coat) was prepared by mixing rofecoxib (50.00 g), microcrystalline cellulose (250.00 g), lactose monohydrate (177.6 g), corn starch (57.00 g) and povidone (25.00 g). This mixture was wetted with a mixture of alcohol (96°, 100.00 ml) and Polysorbate 20 (1.60 g). This wet mixture was then granulated and dried at 40-50°C for 3 hours. The dried granulate was screened and mixed with colloidal silicon dioxide (4.10 g). This mixture was mixed to homogeneity with magnesium stearate (4.70 g). This final mixture was then compressed about the inert coat using biconcave 14.50 mm diameter punches. The coat had a final weight of about 570.0 mg and a hardness of about 7-12 kP.

A final composition (for forming the finish coat) was prepared by mixing HPMC 2910 (12.10 g), PEG 6000 (3.41 g), and titanium dioxide (4.48 g) in a mixture of methylene chloride and alcohol (96°) (70:30 v/v). The final composition was sprayed onto the drug-containing coat in a conventional pan coater to obtain film-coated tablets which membranes weigh about 20 mg.

In one embodiment the weight ratio of COX-II inhibitor to muscle relaxant varies from (12.5:2.2) to (50:8). In one embodiment, the dosage form provides therapeutic plasma levels for the COX-II inhibitor in the range of about 90 ng to about 300 ng per ml of plasma in a subject after administration to the subject.

The above is a detailed description of particular embodiments of the invention. It is recognized that departures from the disclosed embodiments may be made within the scope of the invention and that obvious modifications will occur to a person skilled in the art. Those of skill in the art should, in light of the present disclosure, appreciate that many changes can be made in the specific embodiments which are disclosed herein and still obtain a like or similar result without departing from the spirit and scope of the invention. All of the embodiments disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure.

EXHIBIT A

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

Searching 1976 to present...

Results of Search in 1976 to present db for:
ACLM/"immediate release": 213 patents.
Hits 1 through 50 out of 213

Next 50 Hits

Jump To

Refine Search aclm/"immediate release"

	PAT. NO.		Title
1	6,576,666	T	Nutritional supplements
2	6,572,890	T	Osmotic device containing venlafaxine and an anti-psychotic agent
3	6,572,885	T	Orally administrable opioid formulations having extended duration of effect
4	6,569,857	T	Dietary supplement
5	6,569,463	T	Solid carriers for improved delivery of hydrophobic active ingredients in pharmaceutical compositions
6	6,569,456	T	Osmotic device containing diltiazem and an ACE inhibitor or diuretic
7	6,565,882	T	Antibiotic composition with inhibitor
8	6,562,826	T	Sustained release ranolazine formulations
9	6,558,707	T	Immediate release eplerenone compositions
10	6,558,699	T	High drug load immediate and modified release oral dosage formulations and processes for their manufacture
11	6,557,374	T	Tunnel fire suppression system and methods for selective delivery of breathable fire suppressant directly to fire site
12	6,555,581	T	Levothyroxine compositions and methods
13	6,555,576	T	Method for treating exercise induced asthma
14	6,555,136	T	Pharmaceutical dosage form for pulsatile delivery of methylphenidate
15	6,544,555	T	Antibiotic product, use and formulation thereof
16	6,544,554	T	Regulated release preparations
17	6,541,014	T	Antiviral product, use and formulation thereof
18	6,540,993	T	Method of treating inflammatory bowel disease using a topical formulation of IL-11

19 6,537,573 **T** Combination dosage form comprising cetirizine and pseudoephedrine
20 6,534,093 **T** Immediate release eplerenone compositions
21 6,528,538 **T** Cyclic compounds useful in the treatment of dyslipidaemia, atherosclerosis and diabetes, pharamaceutical compositions and preparation process
22 6,524,619 **T** Dosage forms useful for modifying conditions and functions associated with hearing loss and/or tinnitus
23 6,521,255 **T** Osmotic device containing ranitidine and a prokinetic agent
24 6,521,253 **T** Immediate release tablet
25 6,517,866 **T** Sertraline salts and sustained-release dosage forms of sertraline
26 6,514,531 **T** Controlled-release dosage forms comprising zolpidem or a salt thereof
27 6,509,499 **T** Nitromethylthiobenzene derivatives as inhibitors of aldose reductase
28 6,505,597 **T** Cleansing oil filter containing quick-release liquid antioxidant/additive solution, and method of using same to convert an engine from petroleum-based oil to botanically-based oil
29 6,500,457 **T** Oral pharmaceutical dosage forms for pulsatile delivery of an antiarrhythmic agent
30 6,500,454 **T** Timed, sustained release systems for propranolol
31 6,495,162 **T** Controlled release oral tablet having a unitary core
32 6,485,746 **T** Controlled-release sedative-hypnotic compositions and methods related thereto
33 6,482,437 **T** Morphine sulfate microgranules, manufacturing process and pharmaceutical preparations
34 6,469,035 **T** Methods of pretreating hyperlipidemic individuals with a flush inhibiting agent prior to the start of single daily dose nicotinic acid therapy to reduce flushing provoked by nicotinic acid
35 6,465,012 **T** Pharmaceutical tablet formulation containing gabapentin with improved physical and chemical characteristics and method of making the same
36 6,455,557 **T** Method of reducing somnolence in patients treated with tizanidine
37 6,451,808 **T** Inhibition of emetic effect of metformin with 5-HT3 receptor antagonists
38 6,428,049 **T** Seat belt release mechanism
39 6,423,339 **T** Liquisolid systems and methods of preparing same
40 6,419,960 **T** Controlled release formulations having rapid onset and rapid decline of effective plasma drug concentrations
41 6,410,054 **T** Immediate release eplerenone compositions
42 6,406,715 **T** Intermediate release nicotinic acid compositions for treating hyperlipidemia having unique urinary metabolite profiles
43 6,399,100 **T** Controlled release pharmaceutical compositions containing tiagabine
44 6,387,404 **T** Immediate release tablet cores of insoluble drugs having sustained-release coating
45 6,372,255 **T** Tablet for instant and prolonged release of one or more active substances
46 6,372,254 **T** Press coated, pulsatile drug delivery system suitable for oral administration
47 6,372,252 **T** Guaifenesin sustained release formulation and tablets
48 6,368,634 **T** High release solid preparation, preparation and use thereof
49 6,344,215 **T** Methylphenidate modified release formulations
50 6,342,245 **T** Compositions of lipid lowering agents

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ACLM/"immediate release": 213 patents.
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Refine Search aclm/"immediate release"

	PAT. NO.	Title
51	6,340,476	**T** Pharmaceutical dosage form for pulsatile delivery of methylphenidate
52	6,322,819	**T** Oral pulsed dose drug delivery system
53	6,309,663	**T** Triglyceride-free compositions and methods for enhanced absorption of hydrophilic therapeutic agents
54	6,299,903	**T** Delayed release pharmaceutical formulation containing a .beta.-lactam antibiotic
55	6,297,286	**T** Therapeutic use and formulation
56	6,294,199	**T** Method of treating a bacterial infection comprising administering amoxycillin
57	6,270,807	**T** Taste-masked pharmaceutical composition
58	6,264,973	**T** Apparatus and method for anesthetizing the cervical region of a female
59	6,258,846	**T** Nutritional supplements
60	6,254,891	**T** Extended release acetaminophen
61	6,248,363	**T** Solid carriers for improved delivery of active ingredients in pharmaceutical compositions
62	6,238,702	**T** High load formulations and methods for providing prolonged local anesthesia
63	6,238,699	**T** Pharmaceutical formulations containing a combination of carbidopa and levidopa
64	6,228,398	**T** Multiparticulate modified release composition
65	6,221,394	**T** Dosage forms
66	6,214,379	**T** Maximizing effectiveness of substances used to improve health and well being
67	6,210,714	**T** Immediate release tablet cores of acetaminophen having sustained-release coating
68	6,207,190	**T** Dosage forms for the treatment of the chronic glaucomas

69 6,197,329 T Anti-nausea compositions and methods
70 6,194,000 T Analgesic immediate and controlled release pharmaceutical composition
71 6,191,151 T Therapy for herpes neurological viral conditions utilizing 1,4-dihydropyridine calcium channel blockers
72 6,183,861 T Conformable composite chemical barrier closure and attachment tape
73 6,183,780 T Oral delayed immediate release formulation and method for preparing the same
74 6,183,778 T Pharmaceutical tablet capable of liberating one or more drugs at different release rates
75 6,174,890 T Anti-stress, anti-impairment and anti-aging drug and process for manufacturing thereof
76 6,174,514 T Breath Freshening chewing gum with encapsulations
77 6,171,618 T Combination dosage form comprising cetirizine and pseudoephedrine
78 6,168,805 T Aqueous process for manufacturing paroxetine solid dispersions
79 6,156,342 T Controlled release oral dosage form
80 6,143,327 T Delayed release coated tablet of bupropion hydrochloride
81 6,143,325 T Nefazodone dosage form
82 6,131,026 T Release resource message transmission for unsupported calling service calls
83 6,126,967 T Extended release acetaminophen particles
84 6,126,933 T Methods of treating inflammatory bowel diseases by administering IL-11
85 6,119,688 T Powder dispenser
86 6,110,494 T Cisapride mini-tablet formulations
87 6,106,861 T Multiparticulate tablet disintegrating in less than 40 seconds in the mouth
88 6,103,219 T Pharmaceutical excipient having improved compressibility
89 6,099,859 T Controlled release oral tablet having a unitary core
90 6,096,696 T Alkaline composition for removing protein deposits
91 6,096,341 T Delayed release tablet of bupropion hydrochloride
92 6,096,337 T Liquisolid systems and methods of preparing same
93 6,090,830 T Controlled release compositions and methods for the treatment of hyperlipidemia
94 6,077,537 T Non-sedating acrivastine product
95 6,077,533 T Powder-layered oral dosage forms
96 6,076,074 T System and method for intraday netting payment finality
97 6,074,670 T Fenofibrate pharmaceutical composition having high bioavailability and method for preparing it
98 6,068,854 T Sol-controlled thermocolloid matrix based on gelatin for oral sustained-release form
99 6,066,339 T Oral morphine multiparticulate formulation
100 6,066,332 T Immediate-effect ibuprofen-containing medicament and its use

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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ACLM/"immediate release": 213 patents.
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Refine Search aclm/"immediate release"

PAT. NO.		Title
101	6,056,968	**T** Pharmaceutical drug dosage forms providing different release rates
102	6,046,187	**T** Formulations and methods for providing prolonged local anesthesia
103	6,043,281	**T** Nitromethyl ketones, process for preparing them and compositions containing them
104	6,039,974	**T** Pharmaceutical composition for combination of piperidinoalkanol-decongestant
105	6,033,686	**T** Controlled release tablet of bupropion hydrochloride
106	6,024,982	**T** Immediate release tablet cores of insoluble drugs having sustained-release coating
107	6,015,395	**T** Lower back support
108	6,010,718	**T** Extended release formulations of erythromycin derivatives
109	6,004,582	**T** Multi-layered osmotic device
110	5,989,535	**T** Polymeric bioadhesive emulsions and suspensions and methods of treatment
111	5,985,843	**T** Pharmaceutical composition containing sucralfate
112	5,981,555	**T** Compositions, kits and methods for administration of antilipemic drugs
113	5,958,458	**T** Pharmaceutical multiple unit particulate formulation in the form of coated cores
114	5,955,500	**T** Pharmaceutical compositions containing non-racemic verapamil and process for optimizing the pharmaceutical activity of R- and S-verapamil
115	5,945,123	**T** Maximizing effectiveness of substances used to improve health and well being
116	5,942,241	**T** Formulations and methods for providing prolonged local anesthesia
117	5,932,765	**T** Nitromethyl ketones, process for preparing them and compositions containing them
118	5,932,245	**T** Gelatin or collagen hydrolysate containing drug formulation that provides for immediate

release of nanoparticle drug compounds

119 5,922,340 T High load formulations and methods for providing prolonged local anesthesia

120 5,869,084 T Multi-vitamin and mineral supplements for women

121 5,858,412 T Sustained release formulations utilizing pharmaceutical excipient having improved compressibility with modified microcrystalline

122 5,837,277 T Palatable pharmaceutical compositions

123 5,807,579 T Pseudoephedrine combination pharmaceutical compositions

124 5,795,592 T Pharmaceutical composition to enhance tissue healing and regeneration and application kit comprising it

125 5,792,109 T Irrigation pump and system

126 5,785,994 T Method for administering drug to gastrointestinal tract

127 5,773,453 T Methods for administration of antilipemic drugs

128 5,756,125 T Controlled release naproxen sodium plus naproxen combination tablet

129 5,747,060 T Prolonged local anesthesia with colchicine

130 5,741,524 T Sustained-release formulations utilizing pharmaceutical excipient having improved compressibility

131 5,707,652 T Methods of treating circadian rhythm phase disorders

132 5,650,169 T Pharmaceutical tablet capable of releasing the active ingredients contained therein at subsequent times

133 5,645,858 T Multilayered controlled release pharmaceutical dosage form

134 5,633,285 T Cytoprotective wound healing compositions and methods for preparing and using same

135 5,609,909 T Prolamine coatings for taste masking

136 5,609,884 T Controlled release naproxen sodium plus naproxen combination tablet

137 5,595,762 T Stabilized pulverulent active agents, compositions containing them, process for obtaining them and their applications

138 5,578,316 T Palatable pharmaceutical compositions

139 5,576,022 T Controlled release tacrine drug delivery systems and methods for preparing same

140 5,574,315 T Method and apparatus enabling emergency activated control of electrically operated door lock and window regulator systems in a motor vehicle

141 5,558,879 T Controlled release formulation for water soluble drugs in which a passageway is formed in situ

142 5,508,044 T Diltiazem pharmaceutical spheroid formulation

143 5,500,227 T Immediate release tablet cores of insoluble drugs having sustained-release coating

144 5,492,700 T Process and composition for the development of controlled release gemfibrozil dosage form

145 5,487,901 T Process for preparing pharmaceutical tablet capable of releasing the active ingredients contained therein at subsequent times

146 5,480,650 T Programmed release tablets containing naproxen

147 5,478,577 T Method of treating pain by administering 24 hour oral opioid formulations exhibiting rapid rate of initial rise of plasma drug level

148 5,478,573 T Delayed, sustained-release propranolol pharmaceutical preparation

149 5,445,829 T Extended release pharmaceutical formulations

150 5,411,745 T Powder-layered morphine sulfate formulations

EXHIBIT B

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

Searching 1976 to present...

Results of Search in 1976 to present db for:
ACLM/"delayed release": 247 patents.
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Refine Search aclm/"delayed release"

	PAT. NO.		Title
1	6,576,666	T	Nutritional supplements
2	6,569,857	T	Dietary supplement
3	6,569,463	T	Solid carriers for improved delivery of hydrophobic active ingredients in pharmaceutical compositions
4	6,569,456	T	Osmotic device containing diltiazem and an ACE inhibitor or diuretic
5	6,565,882	T	Antibiotic composition with inhibitor
6	6,558,701	T	Multilayer tablet for administering a fixed combination of tramadol and diclofenac
7	6,555,137	T	Sucralfate-containing composition and process for the preparation thereof
8	6,555,136	T	Pharmaceutical dosage form for pulsatile delivery of methylphenidate
9	6,551,617	T	Taste masking coating composition
10	6,548,084	T	Controlled release compositions
11	6,544,555	T	Antibiotic product, use and formulation thereof
12	6,541,425	T	Retarding formulations of active substances used for plant protection
13	6,541,014	T	Antiviral product, use and formulation thereof
14	6,534,549	T	Controlled release formulations
15	6,528,090	T	Controlled release formulation of divalproex sodium
16	6,515,010	T	Carvedilol methanesulfonate
17	6,511,678	T	Controlled release formulation of divalproex sodium
18	6,509,031	T	System for polymerizing collagen and collagen composites in situ for a tissue compatible wound sealant, delivery vehicle, binding agent and/or chemically modifiable matrix
19	6,500,457	T	Oral pharmaceutical dosage forms for pulsatile delivery of an antiarrhythmic agent

20 6,500,455 **T** Tolperison-containing, pharmaceutical preparation for oral administration
21 6,498,153 **T** Extended release growth promoting two component composition
22 6,490,245 **T** Method and apparatus for recovering from a signalling failure in a switched connection data transmission network
23 6,485,746 **T** Controlled-release sedative-hypnotic compositions and methods related thereto
24 6,485,745 **T** Solid oral dosage forms of valsartan
25 6,468,959 **T** Peroral dosage form for peptide containing medicaments, in particular insulin
26 6,460,446 **T** Sonic rarefaction wave recoilless gun system
27 6,458,383 **T** Pharmaceutical dosage form for oral administration of hydrophilic drugs, particularly low molecular weight heparin
28 6,436,438 **T** Tramadol multiple unit formulations
29 6,428,788 **T** Compositions and methods for specifically targeting tumors
30 6,403,634 **T** Use of taxoid derivatives
31 6,403,597 **T** Administration of phosphodiesterase inhibitors for the treatment of premature ejaculation
32 6,401,819 **T** Methods for deposition of materials in underground reservoirs
33 6,395,727 **T** Method of treating Bulimia Nervosa and related eating disorders by administration of atypical antipsychotic medications
34 6,387,924 **T** Benzothiepines having activity as inhibitors of ileal bile acid transport and taurocholate uptake
35 6,372,799 **T** Non-sedating diphenhydramine metabolites
36 6,368,580 **T** Composition suitable as food integrator and for the treatment of intestinal disorders and alterations of the bacterial flora
37 6,358,528 **T** Pharmaceutical formulation
38 6,352,721 **T** Combined diffusion/osmotic pumping drug delivery system
39 6,350,471 **T** Tablet comprising a delayed release coating
40 6,340,476 **T** Pharmaceutical dosage form for pulsatile delivery of methylphenidate
41 6,338,847 **T** Compositions and methods to disinfect contact lenses
42 6,335,351 **T** Hydroxylansoprazole compositions and methods
43 6,309,893 **T** Assay method with improved release of soluble reagents
44 6,309,663 **T** Triglyceride-free compositions and methods for enhanced absorption of hydrophilic therapeutic agents
45 6,300,343 **T** Method of treatment
46 6,299,903 **T** Delayed release pharmaceutical formulation containing a .beta.-lactam antibiotic
47 6,280,744 **T** Use of inorganic aerogels in pharmacy
48 6,270,805 **T** Two pellet controlled release formulation for water soluble drugs which contains an alkaline metal stearate
49 6,270,798 **T** Lozenge for the modified releasing of active substances in the gastrointestinal tract
50 6,267,990 **T** Controlled-release pharmaceutical preparation comprising an ACE inhibitor as active ingredient

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Refine Search aclm/"delayed release"

	PAT. NO.		Title
51	6,258,846	T	Nutritional supplements
52	6,258,591	T	One-pack preparation for disinfection, neutralization and cleaning of contact lenses and method of disinfection, neutralization and cleaning
53	6,251,429	T	Programmed release ambroxol--HCl dosage forms
54	6,248,363	T	Solid carriers for improved delivery of active ingredients in pharmaceutical compositions
55	6,232,274	T	Viscoelastic surfactant based gelling composition for wellbore service fluids
56	6,221,393	T	Pharmaceutical compositions in the form of sustained-release tablets based on high molecular weight polysaccharide granules
57	6,218,421	T	Method of promoting smoking cessation
58	6,217,904	T	Pharmaceutical dosage form for pulsatile delivery of d-threo-methylphenidate and a second CNS stimulant
59	6,214,379	T	Maximizing effectiveness of substances used to improve health and well being
60	6,210,639	T	Apparatus, method and composition for cleaning and disinfecting
61	6,187,720	T	Delayed release breakers in gelled hydrocarbons
62	6,174,899	T	Orally administered analgesic composition comprising myfadol
63	6,165,415	T	Systems and methods for disinfecting contact lenses
64	6,162,463	T	Extended release formulation of diltiazem hydrochloride
65	6,159,501	T	Modified release multiple-units dosage composition for release of opioid compounds
66	6,143,327	T	Delayed release coated tablet of bupropion hydrochloride

67 6,132,773 T Method for preparing particles comprising a core and a silica shell
68 6,114,382 T Methods for treating inflammatory bowel disease
69 6,103,263 T Delayed pulse release hydrogel matrix tablet
70 6,096,696 T Alkaline composition for removing protein deposits
71 6,096,341 T Delayed release tablet of bupropion hydrochloride
72 6,083,520 T Bioactive feed
73 6,071,959 T Pharmaceutical products containing a complex of an amide-type local anesthetic and a polyacrylate
74 6,020,002 T Delivery of controlled-release system(s)
75 6,004,546 T Pharmaceutical composition containing bismuth-polyacrylic acid compounds
76 5,993,505 T Controlled release fertilizer compositions and processes for the preparation thereof
77 5,985,843 T Pharmaceutical composition containing sucralfate
78 5,985,319 T Multi-phase compositions for an initial and delayed release of a vaginal medicament
79 5,958,873 T Oral formulation for treatment of bacteria-induced diseases of the colon
80 5,948,735 T Use of breaker chemicals in gelled hydrocarbons
81 5,948,248 T Coolant filter having a delayed release supplemental coolant additive cartridge
82 5,945,123 T Maximizing effectiveness of substances used to improve health and well being
83 5,925,344 T Pharmaceutical composition and uses therefor
84 5,922,352 T Once daily calcium channel blocker tablet having a delayed release core
85 5,922,317 T Accelerated gas removal from divers' tissues utilizing gas metabolizing bacteria
86 5,910,322 T Delayed release pharmaceutical formulation containing amoxycillin and potassium clavulanate
87 5,908,829 T Use of MCP-1 for inducing ripening of the cervix
88 5,908,634 T Animal feed containing molasses bentonite and zeolite
89 5,889,028 T Colonic delivery of nicotine to treat inflammatory bowel disease
90 5,871,776 T Controlled-release nifedipine
91 5,853,762 T Delivery of controlled-release system(s)
92 5,846,983 T Colonic delivery of nicotine to treat inflammatory bowel disease
93 5,844,072 T Antibiotic cryptdin peptides and methods of their use
94 5,843,482 T Products and processes for the treatment of the alimentary canal
95 5,795,592 T Pharmaceutical composition to enhance tissue healing and regeneration and application kit comprising it
96 5,783,532 T Enzyme compositions and methods for contact lens cleaning
97 5,767,066 T Medical application of bromelain
98 5,760,093 T Halohydrocarbon-free delayed release lacquer solution for pharmaceutical preparation
99 5,756,125 T Controlled release naproxen sodium plus naproxen combination tablet
100 5,747,438 T Machine dishwashing detergent containing coated percarbonate and an acidification agent to provide delayed lowered pH

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Refine Search aclm/"delayed release"

	PAT. NO.		Title
101	5,733,577	T	Delivery of controlled-release system (s)
102	5,717,087	T	Thermoplastic and biodegradable polysaccharide esters/polysaccharide ether esters containing maleic acid addition product groups
103	5,716,923	T	Laundry detergent containing a coated percarbonate and an acidification agent to provide delayed lowered pH
104	5,711,961	T	Pharmaceutical compositions based on chewing gum and a method for the preparation thereof
105	5,710,181	T	Inhibition of nitric oxide formation in inflammatory bowel disease
106	5,693,340	T	Delayed-release form for pharmaceutical active compounds
107	5,681,588	T	Delayed release microtablet of .beta.-phenylpropiophenone derivatives
108	5,678,632	T	Acidizing underground reservoirs
109	5,667,803	T	Starch acetate composition with modifiable properties, method for preparation and usage thereof
110	5,662,935	T	Process for preparing controlled release pharmaceutical forms and the forms thus obtained
111	5,649,596	T	Use of breaker chemicals in gelled hydrocarbons
112	5,645,848	T	Controlled release composition for active substances into an aqueous medium
113	5,631,296	T	Drugs containing S(+)-ibuprofen
114	5,629,018	T	Composition for controlled release of an active substance and method for the preparation of such a composition
		T	

115 5,622,721 Dosage forms of risedronate
116 5,622,716 T Process for preparing a retard product containing diltiazem for a single daily administration
117 5,618,544 T Method of decreasing cutaneous senescence
118 5,609,884 T Controlled release naproxen sodium plus naproxen combination tablet
119 5,595,762 T Stabilized pulverulent active agents, compositions containing them, process for obtaining them and their applications
120 5,591,397 T Double redox system for disinfecting contact lenses
121 5,578,240 T Compositions and methods for identifying a solution
122 5,574,097 T Chemical compounds
123 5,536,507 T Colonic drug delivery system
124 5,534,250 T Polymers containing diester units
125 5,522,175 T Natural savory and umami flavoring materials from dehydrated mushroom
126 5,505,963 T Slow release pharmaceutical preparation
127 5,498,515 T Photographic element containing a certain sulfonated acylacetanilide coupler in combination with low- or non-chloride emulsions
128 5,496,376 T Carbonate built laundry detergent composition containing a delayed release polymer
129 5,484,609 T Therapeutic compositions and methods
130 5,470,584 T Diltiazem formulation
131 5,462,848 T Color photographic materials including magenta coupler, inhibitor-releasing coupler and carbonamide compound, and methods
132 5,462,713 T Double redox system for disinfecting contact lenses
133 5,455,987 T One-piece hinge
134 5,453,283 T Orally administered solvent-free pharmaceutical preparation with delayed active-substance release, and a method of preparing the preparation
135 5,453,216 T Delayed-release encapsulated warewashing composition and process of use
136 5,451,493 T Photographic element containing a certain sulfonated acylacetanilide coupler in combination with a development inhibitor releasing coupler
137 5,439,689 T Diltiazem formulation
138 5,430,030 T Nerve gas antidote
139 5,427,592 T Intact seed-based delayed-released nutrient supplement for mushroom cultivation
140 5,426,120 T Pharmaceutical composition containing .gamma.-hydroxybutyric acid or its lactone in the treatment of drug dependence and nutritional disorders
141 5,422,117 T Multiphase pharmaceutical formulations
142 5,413,793 T Multiphase suppository
143 5,393,525 T Contrast medium comprising superparamagnetic or ferromagnetic particles capable of increasing viscosity after administration
144 5,378,472 T Methyl pyrrolidinone chitosan, production process and uses thereof
145 5,376,519 T Photographic material containing a coupler composition comprising magenta coupler, phenolic solvent, and at least one aniline or amine
146 5,338,480 T Compositions and methods to clean contact lenses
147 5,336,434 T Methods, compositions and apparatus to disinfect lenses
148 5,334,396 T Chewing gum sweetened with alitame and having a high level of lecithin
149 5,324,447 T Method and activator compositions to disinfect lenses

EXHIBIT C

USPTO Patent Full-Text and Image Database

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Results of Search in 1976 to present db for:
ACLM/"slow release": 508 patents.
*Hits 1 through **50** out of **508***

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Refine Search aclm/"slow release"

	PAT. NO.		Title
1	6,574,913	T	Semiochemical and sonic signals for monitoring and control of clothes moths
2	6,566,338	T	Caspase inhibitors for the treatment and prevention of chemotherapy and radiation therapy induced cell death
3	6,565,866	T	Iodophor compositions
4	6,565,860	T	Surfactant coated products and methods for their use in promoting plant growth and soil remediation
5	6,558,544	T	Pressure vessels for holding cylindrical semipermeable membrane cartridges
6	6,553,726	T	Barrier against crawling arthropods
7	6,552,050	T	Method for enhancing protective cellular responses to genotoxic stress in skin
8	6,547,747		Withdrawn
9	6,544,554	T	Regulated release preparations
10	6,528,049	T	Bisexual attractants, aggregants and arrestants for adults and larvae of codling moth and other species of lepidoptera
11	6,524,333	T	Device for therapeutical treatment of a blood vessel
12	6,514,531	T	Controlled-release dosage forms comprising zolpidem or a salt thereof
13	6,506,422	T	Nutritional formula for phenylketonuria patients
14	6,503,881	T	Compositions and methods for treating infections using cationic peptides alone or in combination with antibiotics
15	6,503,288	T	Process for the production of biodegradable encapsulated fertilizers
16	6,500,222	T	Diureides and their use
17	6,498,152	T	Use of a farnesyl transferase inhibitor in the manufacture of a medicament for local

administration to the vascular wall in the prevention of restenosis

18 6,495,563 T Method and composition for prevention of scar formation in glaucoma filtration bleb and drainage fistula

19 6,495,522 T Substituted alpha-hydroxy acid caspase inhibitors and the use thereof

20 6,472,198 T Slow release substrates for driving microbial transformations of environmental contaminants

21 6,464,961 T Polymeric delivery and release systems for oral care actives

22 6,464,875 T Food, animal, vegetable and food preparation byproduct treatment apparatus and process

23 6,464,864 T Composition for treating aqueous composition contaminants

24 6,464,746 T Homogeneous granules of slow-release fertilizer and method of making the same

25 6,458,386 T Medicaments based on polymers composed of methacrylamide-modified gelatin

26 6,455,569 T Connective tissue softening

27 6,455,542 T Piperidine and pyrrolidine derivatives comprising a nitric oxide donor for treating stress

28 6,451,765 T Methods for treating breast cancer using Mammastatin

29 6,448,288 T Cannabinoid drugs

30 6,448,267 T Piperidine and pyrrolidine derivatives comprising a nitric oxide donor for treating stress

31 6,445,796 T Automatic telephone-line disconnect system

32 6,440,427 T Tissue treatment composition comprising fibrin or fibrinogen and biodegradable and biocompatible polymer

33 6,440,393 T Carbon dioxide enhancement of inhalation therapy

34 6,428,785 T Method and composition for treating prostate cancer

35 6,391,911 T Coadministration of lucanthone and radiation for treatment of cancer

36 6,389,745 T Sheet for growing grass seeds and grass seed mat using same

37 6,387,145 T Fine granulated fertilizer formulation for seed/plant placement at seeding or transplanting

38 6,383,516 T Sustained-release microgranules containing diltiazem as active principle

39 6,372,238 T Method of using implants to fertilize, control growth and fungal and insect attack on banana or plantain

40 6,370,820 T Self-watering vertical supporting planter

41 6,364,925 T Polyurethane encapsulated fertilizer having improved slow-release properties

42 6,358,954 T PDGF receptor kinase inhibitory compounds, their preparation, purification and pharmaceutical compositions including same

43 6,358,939 T Use of biologically active vitamin D compounds for the prevention and treatment of inflammatory bowel disease

44 6,358,296 T Slow-release polyurethane encapsulated fertilizer using oleo polyols

45 6,344,208 T Pheromone baits for social insects

46 6,338,387 T Downward energized motion jars

47 6,337,329 T Oxazolidinones to treat eye infections

48 6,336,949 T Slow release urea fertilizer composition and a process for the preparation of the said composition

49 6,335,331 T Pseudopolymorphic forms of 2-[2-[4-[Bis (4-fluorophenyl) methyl]-1-piperazinyl]ethoxy] acetic acid dihydrochloride

50 6,328,959 T Intestinal hydrogen removal using hydrogen-metabolizing microbes

USPTO Patent Full-Text and Image Database

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Results of Search in 1976 to present db for:
ACLM/"slow release": 508 patents.
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Refine Search aclm/"slow release"

	PAT. NO.		Title
51	6,326,022	T	Slow-release disposable elastomeric buccal devices
52	6,325,934	T	Enzyme and bacterial combination in a slowly dissolvable matrix for septic tanks, grease traps and waste treatment
53	6,316,427	T	Treatment for diabetes
54	6,316,031	T	Stabilized controlled release substrate having a coating derived from an aqueous dispersion of hydrophobic polymer
55	6,316,008	T	Combination of zinc ions and vitamin C and method of making
56	6,312,705	T	Iodophor compositions
57	6,309,370	T	Intracardiac drug delivery
58	6,306,804	T	Bilge Cleaning Product
59	6,297,213	T	Osteogenic devices
60	6,290,990	T	Slow-release matrix pellets and the production thereof
61	RE37,369	T	Slow release coolant filter
62	6,287,849	T	Microbiological testing of a liquid sample
63	6,280,772	T	Polyester/carboxylic acid composite materials
64	6,277,932	T	Polymerization processes and products
65	6,277,411	T	Pharmaceutical formulation containing DFMO for the treatment of cancer
66	6,264,939	T	Bisexual attractants, aggregants and arrestants for adults and larvae of codling moth and other species of lepidoptera

67 6,261,997 **T** Slow release formulations of pesticides
68 RE37,262 **T** Herbal compositions for treatment of gastrointestinal disorders
69 6,242,381 **T** Influencing the activity of plant growth regulators
70 6,238,554 **T** Fuel filter including slow release additive
71 6,225,258 **T** Controlled release pesticide and fertilizer briquettes
72 6,217,770 **T** Apparatus and method for treatment of water
73 6,214,377 **T** Melatonin for the production of a peroral pulsatile form of medication
74 6,209,646 **T** Controlling the release of chemical additives in well treating fluids
75 6,206,945 **T** Method of producing artificial guano
76 6,199,316 **T** Apparatus for providing a slow release of a compressed gas and an insect trap incorporating same
77 6,197,757 **T** Particles, especially microparticles or nanoparticles, of crosslinked monosaccharides and oligosaccharides, processes for their preparation and cosmetic, pharmaceutical or food compositions in which they are present
78 6,192,623 **T** Plant feeder for long term, low maintenance and accurate feeding of potted plants
79 6,192,128 **T** Current-sensitive telephone-line disconnect system
80 6,180,661 **T** Bioflavonol-glycoside peresters and their incorporation into pharmacologically active concentrates and ultramicroemulsions
81 6,180,127 **T** Slow release insect repellents
82 6,174,917 **T** Method of treating liver disease and like indications with vasodilating agents
83 6,174,549 **T** Gel products from plant matter
84 6,165,550 **T** Symmetrical Polyurea-urethane fertilizer encapsulation
85 6,159,460 **T** Method for treating interleukin-1 mediated diseases
86 6,156,738 **T** Diabetic supplement bar
87 6,153,094 **T** Wastewater treatment method and apparatus
88 6,152,981 **T** Sulfur containing isocyanate compositions
89 6,149,960 **T** Process and formulation for a chemically leavened dough or bakery product
90 6,146,589 **T** Assay device for detecting the presence of an analyte involving sequential delivery of reagents through a liquid circuit
91 6,139,860 **T** Method of stimulating cilia
92 6,138,289 **T** Automatic toilet seat lowering device
93 6,133,320 **T** Treatment of osteoporosis and metabolic bone disorders with nitric oxide substrate and/or donors
94 6,132,772 **T** Extended-release solid oral dosage forms of drugs having low solubility in water
95 6,132,768 **T** Oral pharmaceutical composition with delayed release of active ingredient for reversible proton pump inhibitors
96 6,132,759 **T** Medicaments containing gelatin cross-linked with oxidized polysaccharides
97 6,132,710 **T** Preventing/treating neonatal NEC by administering lactobacillus salivarius and lactobacillus plantarum or a combination thereof
98 6,121,249 **T** Treatment and prevention of cardiovascular diseases with help of aspirin, antioxidants, niacin, and certain B vitamins
99 6,120,574 **T** Slow release fertilizer spike
100 6,117,856 **T** Topical bisphosphonates for prevention of bone resorption

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

Searching 1976 to present...

Results of Search in 1976 to present db for:
ACLM/"slow release": 508 patents.
*Hits **101** through **150** out of **508***

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Refine Search aclm/"slow release"

PAT. NO.		Title
101	6,110,866	**T** Surfactant coated products and methods for their use in promoting plant growth
102	6,106,836	**T** Container with freeze-dried vaccine components
103	6,105,831	**T** Pitcher-style reusable bottle holder
104	6,080,221	**T** Vacuum coated particulate fertilizers
105	6,079,145	**T** Fishing lure
106	6,078,793	**T** High precision controlled gain voice processing system and method
107	6,077,867	**T** Pig appeasing pheromones to decrease stress, anxiety and aggressiveness
108	6,075,032	**T** Method of preventing proliferation of retinal pigment epithelium by retinoic acid receptor agonists
109	6,074,673	**T** Slow-release, self-absorbing, drug delivery system
110	6,071,926	**T** Sleep quality improvement using a growth hormone secretagogue
111	6,071,924	**T** Method of preventing proliferation of retinal pigment epithelium by retinoic acid receptor agonists
112	6,064,900	**T** Monitoring systems
113	6,060,077	**T** Unit galenical formulation for local hormonotherapy of vaginal dryness
114	6,057,359	**T** Spontaneously dispersible concentrates comprising esters of baccatin-III compounds having antitumor and antiviral activity
115	6,054,400	**T** Bioactive glasses and their use
116	6,050,368	**T** Procedure and apparatus for controlling the hoisting motor of an elevator

117 6,048,337 **T** Transdermal perfusion of fluids
118 6,039,954 **T** Herbal compositions for treatment of gastrointestinal disorders
119 6,034,057 **T** Peptide inhibitors of fibronectine
120 6,034,056 **T** Fibronectin adhesion inhibitors
121 6,022,827 **T** Sod or other vegetation having a root support matrix with beneficial plant adjuvants thereon
122 6,010,712 **T** Therapeutic use of bFGF to treat conditions involving adhesion of cytotoxic white cells to endothelium
123 6,004,260 **T** Intrauterine delivery arrangement
124 6,001,147 **T** Unsymmetrical polyureaurethane fertilizer encapsulation
125 5,998,485 **T** Method for modulating immune response with inositol
126 5,994,402 **T** Anti-inflammatory and anti-pyretic method
127 5,990,183 **T** Porous particles, porous hollow particles and method of preparing such particles
128 5,985,907 **T** Method for inhibiting growth of methanogens
129 5,984,994 **T** Sulfur coated fertilizers with improved abrasion resistance
130 5,981,590 **T** Oral glutamine in the prevention of neonatal necrotizing enterocolitis and other gastrointestinal mucosal damage
131 5,981,469 **T** 78 residue polypeptide (NK-lysine) and its use
132 5,980,952 **T** Pharmaceutical composition for the programmed release of dexfenfluramine
133 5,980,739 **T** Wastewater treatment method and apparatus
134 5,977,175 **T** Methods and compositions for improving digestion and absorption in the small intestine
135 5,965,567 **T** Method for treating nicotine addiction
136 5,962,016 **T** Multivesicular liposomes utilizing neutral lipids to modify in vivo release
137 5,958,463 **T** Agricultural pesticide formulations
138 5,958,452 **T** Extruded orally administrable opioid formulations
139 5,948,757 **T** High dose IGF-1 therapy
140 5,945,124 **T** Oral pharmaceutical composition with delayed release of active ingredient for pantoprazole
141 5,932,580 **T** PDGF receptor kinase inhibitory compounds their preparation and compositions
142 5,932,248 **T** Controlled release preparations for cytotoxic or cytostatic drugs
143 5,927,610 **T** Fertilizer dispensing apparatus
144 5,927,006 **T** Ready roots
145 5,914,134 **T** Process for the pulsatile delivery of diltiazem HCL and product produced thereby
146 5,905,069 **T** Methods of decreasing or preventing pain using spicamycin or derivatives thereof
147 5,900,244 **T** Insect attractant
148 5,898,038 **T** Treatment of osteoporosis and metabolic bone disorders with nitric oxide substrate and/or donors
149 5,897,891 **T** Flavorful zinc compositions for oral use incorporating copper
150 5,897,852 **T** Container with freeze-dried vaccine components

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EXHIBIT D

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

Searching 1976 to present...

Results of Search in 1976 to present db for:
ACLM/"rapid release": 156 patents.
*Hits 1 through **50** out of **156***

Next 50 Hits

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Refine Search aclm/"rapid release"

	PAT. NO.		Title
1	6,569,461	T	Dihydroxy open-acid and salts of HMG-CoA reductase inhibitors
2	6,569,456	T	Osmotic device containing diltiazem and an ACE inhibitor or diuretic
3	6,555,127	T	Multi-spike release formulation for oral drug delivery
4	6,542,109	T	Autonomous off-board defensive aids system
5	6,521,255	T	Osmotic device containing ranitidine and a prokinetic agent
6	6,495,154	T	On demand administration of clomipramine and salts thereof to treat premature ejaculation
7	6,491,949	T	Osmotic device within an osmotic device
8	6,475,521	T	Biphasic controlled release delivery system for high solubility pharmaceuticals and method
9	6,468,959	T	Peroral dosage form for peptide containing medicaments, in particular insulin
10	6,451,808	T	Inhibition of emetic effect of metformin with 5-HT3 receptor antagonists
11	6,451,345	T	Functional coating of linezolid microcapsules for taste-masking and associated formulation for oral administration
12	6,290,989	T	Expandable gastro-retentive therapeutic system with controlled active substance release in the gastro-intestinal tract
13	6,284,269	T	Pharmaceutical compositions of meloxicam with improved solubility and bioavailability
14	6,284,264	T	Water soluble film for oral administration with instant wettability
15	6,277,411	T	Pharmaceutical formulation containing DFMO for the treatment of cancer
16	6,274,173	T	Oral pharmaceutical composition with delayed release of active ingredient for pantoprazole
17	6,251,427	T	Pharmaceutical capsule compositions containing loratadine and psuedoephedrine
18	6,248,359	T	Multi-tablet oxybutynin system for treating incontinence
19	6,241,045	T	Safety structures for pole climbing applications

20 6,168,801 T Controlled release drug delivery
21 6,153,218 T Biphasic capsule formulation
22 6,074,580 T Method for the preparation of pearls and pearls obtained containing an active ingredient with an undefined crystallization point
23 6,068,856 T Oral pharmaceutical composition with delayed release of active ingredient for pantoprazole
24 6,066,334 T Use of redispersible polymer powders or polymer granules as binders for producing solid pharmaceutical presentations
25 6,063,821 T Transparent rapid release compositions of non-steroidal analgesics
26 6,060,266 T Self-contained incubator for growth of microorganism
27 6,056,974 T Rapid-release S1452 tablets
28 6,050,384 T Method and apparatus for rapid transmission brake release
29 6,046,177 T Sulfoalkyl ether cyclodextrin based controlled release solid pharmaceutical formulations
30 6,029,947 T Safety valve for fire suppression device
31 5,980,952 T Pharmaceutical composition for the programmed release of dexfenfluramine
32 5,957,741 T Quick release device for surfboard safety leashes
33 5,935,511 T Method of forming and removing thin walled plastic articles from a plurality of dies in a thermoforming apparatus
34 5,925,568 T Release and mobilization of haematopoietic cells
35 5,910,322 T Delayed release pharmaceutical formulation containing amoxycillin and potassium clavulanate
36 5,908,614 T Peroxidase-activating oral compositions
37 5,891,233 T Use of bioactive silicious glass and new compositions containing bioactive silicious glass
38 5,857,854 T Recoil simulator for a weapon
39 5,849,330 T Controlled release pharmaceutical
40 5,823,972 T Pressure transducer bladder pressure and urinary flow measurement apparatus and method
41 5,821,438 T Device to alter an atmosphere in an autoclave
42 5,744,423 T Method and composition for protecting pavement structure from growth of plants in splits of the structure
43 5,700,971 T Rapid-release smoke hand grenade
44 5,695,784 T Flavor-masked pharmaceutical compositions
45 5,667,803 T Starch acetate composition with modifiable properties, method for preparation and usage thereof
46 5,637,320 T Controlled absorption naproxen formulation for once-daily administration
47 5,622,716 T Process for preparing a retard product containing diltiazem for a single daily administration
48 5,616,345 T Controlled absorption diltiazen formulation for once-daily administration
49 5,609,590 T PH-triggered osmotic bursting delivery devices
50 5,606,932 T Implement for automatically milking animals, such as cows

USPTO PATENT FULL-TEXT AND IMAGE DATABASE

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ACLM/"rapid release": 156 patents.
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Refine Search aclm/"rapid release"

	PAT. NO.		Title
51	5,518,285	T	Floor for supporting a load
52	5,512,055	T	Anti-infective and anti-inflammatory releasing systems for medical devices
53	5,490,712	T	Storage of items
54	5,439,689	T	Diltiazem formulation
55	5,437,656	T	Method and device for inhibiting H.I.V. hepatitis B and other viruses and germs when using a needle, scalpel and other sharp instrument in a medical environment
56	5,417,251	T	Programmable weft insertion brake for looms
57	5,398,724	T	High speed electrically actuated gaseous fuel admission valve
58	5,392,861	T	Residual pollution containment device and method of cleaning a wireline
59	5,376,383	T	Method for enhancing the lowering of plasma-cholesterol levels
60	5,370,881	T	Water-soluble delivery systems for hydrophobic liquids
61	5,370,879	T	Formulations and their use in the treatment of neurological diseases
62	5,368,861	T	Gastric preparation with sustained release
63	5,364,620	T	Controlled absorption diltiazem formulation for once daily administration
64	5,358,502	T	PH-triggered osmotic bursting delivery devices
65	5,344,411	T	Method and device for inhibiting HIV, hepatitis B and other viruses and germs when using a catheter in a medical environment
66	5,320,853	T	Controlled release formulation for pharmaceutical compounds
67	5,286,497	T	Diltiazem formulation

68 5,286,044 **T** Belted multi-purpose trailer
69 5,281,279 **T** Process for producing refined sugar from raw juices
70 5,172,881 **T** Adjustable dock support
71 5,135,086 **T** Assembly tool with rapid release electromagnetic clutch
72 5,120,548 **T** Swelling modulated polymeric drug delivery device
73 5,093,200 **T** Multilayer sustained release granule
74 5,084,278 **T** Taste-masked pharmaceutical compositions
75 5,083,771 **T** Novelty item
76 5,050,715 **T** Hydraulic control apparatus for vehicle power transmitting system having fluid coupling incorporating lock-up clutch
77 5,050,498 **T** Stencil manufacturing and printing process and apparatus
78 5,007,200 **T** Window security system
79 5,002,776 **T** Controlled absorption diltiazem formulations
80 4,997,658 **T** Method for enhancing the lowering of plasma cholesterol levels
81 4,978,533 **T** Liquid nifidipine composition
82 4,973,277 **T** Safety belt harness system
83 4,968,505 **T** Long-acting diclofenac sodium preparation
84 4,966,772 **T** DHP delayed release preparation
85 4,962,683 **T** Rotary cutter apparatus
86 4,957,044 **T** Double sided screener for printed circuit boards
87 4,940,292 **T** Rapid release valve mechanism
88 4,933,186 **T** Dihydropyridine depot formulation
89 4,931,177 **T** Composite plate for filter-presses
90 4,926,859 **T** A medical treatment device for treating an undesired formation in a living body
91 4,922,716 **T** Throttled exhaust outlet to reservoir for reducing noise resulting from release hydraulic pressure surges
92 4,894,240 **T** Controlled absorption diltiazem formulation for once-daily administration
93 4,892,741 **T** Press coated DHP tablets
94 4,881,047 **T** Automatic gain expansion system
95 4,866,097 **T** Controlled release system
96 4,863,742 **T** Controlled absorption pharmaceutical composition
97 4,837,030 **T** Novel controlled release formulations of tetracycline compounds
98 4,786,495 **T** Therapeutic agents
99 4,783,335 **T** Controlled topical application of bioactive reagent
100 4,772,473 **T** Nitrofurantoin dosage form

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USPTO Patent Full-Text and Image Database

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ACLM/"rapid release": 156 patents.
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Final 6 Hits

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Refine Search aclm/"rapid release"

	PAT. NO.		Title
101	4,765,990	T	Sustained-release nifedipine preparation
102	4,740,122	T	Rapid-release chuck
103	4,720,387	T	Sustained-release preparation of pinacidil
104	4,713,247	T	Long-acting formulation of cefaclor
105	4,708,184	T	Tire pressure regulating unit
106	4,707,362	T	Sustained release composition
107	4,657,294	T	Front guard bar for motor vehicles
108	4,649,817	T	Stencil manufacturing and printing process
109	4,631,061	T	Automatic urine detecting, collecting and storing device
110	4,630,542	T	Nacelle
111	4,629,620	T	Membrane-coated sustained-release tablets and method
112	4,629,619	T	Membrane-coated sustained-release tablets and method
113	4,615,814	T	Porous substrate with absorbed antistat or softener, used with detergent
114	4,600,577	T	Pharmaceutical preparations of pinacidal
115	4,599,411	T	Process for the production of alkali metal salts of dichloroisocyanuric acid
116	4,561,529	T	Torque-limiting clutch with temperature-responsive rapid release mechanism
117	4,557,925	T	Membrane-coated sustained-release tablets and method
118	4,513,810	T	Low gravity exothermic heating/cooling apparatus
		T	

119 4,510,791 Method and apparatus for testing the air-tightness of a building using transient pressurization
120 4,503,031 **T** Super-fast-starting-sustained release tablet
121 4,498,365 **T** Apparatus for providing extended versatility in a keyboard-controlled musical instrument in pitch variation, tone alteration characteristics and the like
122 4,476,159 **T** High temperature adhesive silicone foam composition, foam generating system and method of generating foam
123 4,470,927 **T** Method of extracting the flavoring substances from the vanilla capsule
124 4,437,872 **T** Apparatus for bending and tempering glass sheets
125 4,413,688 **T** Diverter valve
126 4,384,003 **T** Contraceptive suppository
127 4,347,877 **T** Apparatus for aseptically discharging flowable substances
128 4,336,860 **T** Material handling vehicle having improved deadman control
129 4,303,247 **T** Catapult game
130 4,287,818 **T** Automatic fryer for breaded products
131 4,269,176 **T** Treatment head for electromedical diagnostic or therapeutic treatment of body parts
132 4,253,474 **T** Method for expanding tobacco
133 4,242,544 **T** Multiple-switch arrangement
134 4,233,049 **T** Method and apparatus for shaping glass sheets by drop forming
135 4,229,199 **T** Shaping glass sheets by drop forming with differential vacuum release
136 4,229,119 **T** Liftable and collapsible barrage
137 4,221,637 **T** Liquid absorbent safety rod for a nuclear reactor
138 4,221,573 **T** Electrostatic precipitator rapping mechanism
139 4,191,137 **T** Electronic fuel injection control for an internal combustion engine
140 4,186,902 **T** Snap-lock terminator mounting bracket assembly
141 4,171,827 **T** Ski brake
142 4,122,157 **T** Nitrofurantoin sustained release tablet
143 4,098,333 **T** Marine production riser system
144 4,091,808 **T** Strap for immobilizing human limb during surgery
145 4,080,588 **T** Vehicles and control circuits for vehicle accessories
146 4,073,452 **T** Apparatus for delaying the pressure drop in pressurized cabins or the like especially in an emergency
147 4,061,800 **T** Vapor desposition method
148 4,059,034 **T** Screw-driving devices
149 4,058,862 **T** Water safety device
150 4,057,046 **T** Blood circulation stimulator

EXHIBIT E

http://www.fda.gov/cder/dsm/DRG/drg00201.htm

CDER DATA STANDARDS MANUAL

FDA Data Element Number. None.

CDER Data Element Number. C-DRG-00201

Version Number. 002

Data Element Name. Dosage Form.

Description. This standard provides for all drug dosage forms. The granularity of data often requires that more specific dosage form terms be stored in CDER's automated databases then is represented in its publications. These dosage form terms are available not only use in databases that track approved drug products, but also for drug products such as those that have not been approved, investigational drug products, homeopathic drug products, and bulk drug products.

Source. COMIS Reference table (which is used by the Drug Product Reference File to generate Approved Drug Products with Therapeutic Equivalence Evaluations (aka "The Orange Book")), and the Drug Registration and Listing Database.

Relationship.

FDA Specifications. None.

CDER Specifications. Dosage Form shall consist of an alphabetic term which has a maximum length restricted to 240 characters, with the comma and hyphen being the only punctuation permissible. Codes representing these dosage forms shall consist of three digits.

FDA Approved Date. None.

CDER Approved Date. April 14, 1992.

FDA Revised Date.

CDER Revised Dates. January 12, 1993; October 11, 1994; January 10, 1995; December 12, 1996; November 8, 1996; April 21. 1997; November 14, 1997; February 24, 1998; November 2, 1998; December 21, 2000

TABLET, DELAYED RELEASE PARTICLES	A solid dosage form containing a conglomerate of medicinal particles that have been covered with a coating which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.
TABLET, DELAYED RELEASE	A solid dosage form which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.
TABLET, EXTENDED RELEASE	A solid dosage form containing a drug which allows at least a reduction in dosing frequency as compared to that drug presented in conventional dosage form.
PELLETS, COATED, EXTENDED RELEASE	A solid dosage form in which the drug itself is in the form of granules to which varying amounts of coating have been applied, and which releases a drug (or drugs) in such a manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form
CAPSULE, COATED, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; additionally, the capsule is covered in a designated coating, and which releases a drug (or drugs) in such a manner to allow at least a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.
CAPSULE, COATED PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which varying amounts of coating have been applied.
CAPSULE, DELAYED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) at a time other than promptly after administration. Enteric-coated articles are delayed release dosage forms.
CAPSULE, DELAYED RELEASE PELLETS	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container or "shell" made from a suitable form of gelatin; the drug itself is in the form of granules to which enteric coating has been applied, thus

	delaying release of the drug until its passage into the intestines.
CAPSULE, EXTENDED RELEASE	A solid dosage form in which the drug is enclosed within either a hard or soft soluble container made from a suitable form of gelatin, and which releases a drug (or drugs) in such a manner to allow a reduction in dosing frequency as compared to that drug (or drugs) presented as a conventional dosage form.
GRANULE, FOR SUSPENSION, EXTENDED RELEASE	A small medicinal particle or grain made available in its more stable dry form, to be reconstituted with solvent just before dispensing to form a suspension; the extended release system achieves slow release of the drug over an extended period of time and maintains constant drug levels in the blood or target tissue.

EXHIBIT F

http://www.fda.gov/cder/guidance/1713bpl.pdf

Guidance for Industry: dissolution testing of immediate release solid oral dosage forms.

Table of Contents

Docket No. PHUS-28

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent application of:
FAOUR, J. et al.

Serial No.: 09/770,901
Filed: January 26, 2001

Group Art Unit: 1617
Examiner: Shaojia A. Jiang

For: Pharmaceutical compositions containing A COX-II inhibitor and a muscle relaxant

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

"EXPRESS MAIL" MAILING LABEL NUMBER EU244411606US
DATE OF DEPOSIT: OCTOBER 23, 2003
I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE COMMISSIONER FOR PATENTS.

RICK MATOS
(TYPED OR PRINTED NAME OF PERSON MAILING PAPER OR FEE)

(SIGNATURE OF PERSON MAILING PAPER OR FEE)

SECOND SUPPLEMENTAL DECLARATION UNDER RULE 37 C.F.R. §1.132

Further to the Office Action mailed April 23, 2003, and the Supplemental Declaration mailed September 17, 2002, the undersigned hereby declares as follows:

My name is Ethel C. Feleder. I reside in Luis Maria Campos 449, 2° A, Buenos Aires, Argentina.

I am knowledgeable in the area of Pharmaceutical Sciences and in particular in the area of the clinical evaluation of pharmaceutical formulations. My education, experience, publications and awards are summarized in my curriculum vitae, which has been previously submitted.

I am familiar with the subject matter of the invention disclosed and claimed in the above-identified patent application. In particular, I am familiar with conventional methods of analgesic therapy with individual drugs and with combinations of drugs.

With regard to the subject matter of claims 1-8, 40-45 and 49-54, I understand that the claims cover a pharmaceutical composition comprising a COX-II inhibitor and a muscle relaxant.

With regard to the subject matter of claims 10-38 and 46-48, I understand that the claims cover a pharmaceutical dosage form comprising a COX-II inhibitor and a muscle relaxant.

As a medical doctor, it is my belief that the claimed pharmaceutical compositions and dosage forms provide significant advantages over conventional analgesic compositions and dosage

forms used in pain therapy. In particular, the claimed pharmaceutical composition and dosage form provide an enhanced analgesic affect as compared to the administration of either agent alone AND as compared to the administration of an NSAID and a muscle relaxant. The exemplary formulation of rofecoxib and pridinol, the claimed composition and the claimed dosage form provide an unexpectedly improved analgesic effect over an equidose composition comprising diclofenac (an NSAID) and pridinol.

As previously declared, a side-by-side study to compare the analgesic effects of the claimed composition versus a prior art composition was conducted. The test employed was a writhing test conducted according to the method previously described by Siegmund et al. (*Proc. Soc. Exp. Biol. Med.* (1957), 95, 729-731). The method is well known in the art as a test for determining the analgesic effect of a drug or combination of drugs. The method and results were described in detail in the prior supplemental declaration.

In support of the prior supplemental declaration, this declaration is accompanied by a translation (Exhibits A & B) of a report containing the data of the side-by-side study conducted to compare the analgesic effects of the composition comprising rofecoxib and pridinol versus a prior art composition comprising diclofenac and pridinol.

Based upon the data enclosed herewith, the following results were obtained.

1. When administered alone and at the above-noted doses, neither diclofenac nor rofecoxib nor pridinol provided a statistically significant reduction in the number of contortions observed as compared to control (FIGS. 1-3). This means that the drugs were dosed at subtherapeutic levels considering that both drugs have been reported to produce analgesic effects in different animal models.
2. When diclofenac was administered in combination with pridinol, no statistically significant reduction in the number of contortions was observed as compared to control (FIG. 4). This means that pridinol did not enhance (either additively or synergistically) the analgesic efficacy of diclofenac at the doses tested.
3. When rofecoxib was administered in combination with pridinol, a statistically significant reduction in the number of contortions was observed as compared to control (FIG. 5). This means that pridinol synergistically enhanced the analgesic efficacy of rofecoxib at

the doses tested, since each agent alone did not provide an analgesic effect at the doses tested.

Therefore, it is truly unexpected that the combined administration of a COX-II inhibitor and a muscle relaxant provides an improved, additive or synergistic analgesic effect when administered to a subject as compared to the analgesic effect provided by the administration of either agent alone or as compared to the administration of an NSAID and a muscle relaxant.

I further declare that the statements made herein, to my knowledge, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: 23rd October 2003

Dr. Ethel C. Feleder, M.D., Ph.D.

EXHIBIT A

Table 1: Number of Controtions per 10 minutes for each mouse as a function of drug administered and dosage level.

Dose (mg/kg)	Contortions per 10 minutes in each mouse						Mean'	S.D.
0.0 (Normal saline)	14	17	20	24			18.8	4.3
0.32	28	22	23	16	24	22	22.5	3.9
0.64	14	19	30	23	16	28	21.7	6.5
1.28	21	13	21	22	28	11	19.3	6.3
2.56	13	29	13	25	11	19	18.3	7.3

Diclofenac Sodium

Dose (mg/kg)	Contortions per 10 minutes in each mouse				Mean	S.D.	P value of contr.
0.0 (Normal saline)	14	17	20	24	18.8	4.3	
16	29	14	7	9	14.8	9.9	0.4568
32	13	11	16	3	10.8	5.6	0.5330
64	2	18	0	16	9.0	9.3	0.9275

Rof c xib

Dose (mg/kg)	Contortions per 10 minutes in each mouse											Mean	S.D.	
0.0 (1% CMC)	32	31	36	14								28.3	9.7	
16	12	12	17	10	7	13	2	2	10	18	3	9.6	5.6	0.0004
32	18	15	18	20	7	3	31	10				15.3	8.7	0.0864
64	35	22	25	12	23	17	17	0				18.9	10.2	0.6597

EXHIBIT B

Tabl 2: C nt rtions per 10 minutes for the combination of diclofenac sodium and rofecoxib and pridinol.

Dicl fenac Plus Pridinol

Dose (mg/kg)	Contortions per 10 minutes in each mouse						Mean	S.D.
0.0 (Normal saline)	14	14	35	7	19		17.8	12.1
16	12	26	20	7	9	4	13.0	8.4
32	25	15	15	11	12	37	19.2	6.0
64	20	12	9	21	25	12	16.5	5.9

Rof coxib Plus Pridinol

Dose (mg/kg)	Contortions per 10 minutes in each mouse												Mean	S.D.
0.0 (1% CMC)	33	43	44	56	37	32							40.8	8.9
16	33	7	20	28	13	7	21	13	13	28	2	7	16.0	9.9
32	28	37	25	29	15	16	28	10	20	29	28		24.1	7.9
64	18	29	13	29	11	20	23	6	25	16	13	2	17.1	8.6

Table 3: Two tailed T-Test statistical analysis of the combination of diclofenac & pridinol versus rofecoxib & pridinol

Diclofenac Plus Pridinol

Dose (mg/kg)	P value from Control
0.0 (Normal saline)	
16	0.4208
32	0.8308
64	0.8054

R f coxib Plus Pridinol

Dos (mg/kg)	
0.0 (1% CMC)	
16	0.0001
32	0.0012
64	0.0001